

**COMBINED DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION
AND POWER OF ATTORNEY EXECUTED BY ASSIGNEE FOR REISSUE APPLICATION**

- ☒ Declaration Submitted with Initial Filing OR
☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16(e)) required)

As a representative for the assignee, I hereby declare that:

I believe the named inventors to be original, first, and joint inventors of the subject matter which is claimed and for which a reissue of U.S. Patent 6,114,397 (hereinafter "the original patent") is sought on the invention entitled:

GOSSYPOL FOR THE TREATMENT OF CANCER

the specification of which:

- ☒ is attached hereto.
☐ was filed on as Application No. and was amended on (if applicable).
☐ was filed by Express Mail No. as Application No. not known yet, and was amended on (if applicable).
☐ was filed on as PCT International Application No. PCT/ and was amended on (if any).

I have reviewed and understand the contents of the specification identified above, including the claim(s), as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Foreign priority benefits are claimed under 35 USC 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application(s) designating at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application(s) for patent, utility model, design registration, inventor's or plant breeder's rights certificate(s), or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter and having a filing date before that of the application(s) from which the benefit of priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Claimed		Certified Copy Attached?	
			YES	NO	YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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In re Appln. of Flack et al.
Attorney Docket No. 225011
DHHS Ref. No. E-133-1990/0-US-03

The original patent is believed to be wholly or partly inoperative or invalid by reason of the patentees claiming, without deceptive intent, more than the patentees had the right to claim in the patent. Specifically, the independent claims 1 and 8 of the original patent encompass the use of racemic gossypol to treat cancer in a human. However, it has recently been discovered that the post-operative administration of racemic gossypol to patients, following surgical resection of bladder tumors, was disclosed in a prior art reference unknown to patentees during the prosecution of the original patent. The prior art reference is an article in a Russian medical journal, namely Yerukhimov et al., "Treatment of Bladder Tumors with Gossypol and Ionol in Combination with Surgical Intervention," *Voprosy Onkologii* XII (1966). The prior art reference and the aforementioned error were discovered after issuance of the original patent.

All errors being corrected in the reissue application up to the time of filing of this declaration arose without any deceptive intention of the part of the patentees.

The assignee hereby appoints the National Institutes of Health, Office of Technology Transfer, 6011 Executive Blvd., Ste. 325, Rockville, Maryland 20852-3804, Telephone (301) 496-7056, as Principal Attorneys to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith: Customer Number 05318.

05318

Please recognize Leydig, Voit, & Mayer, Ltd. as Associate Attorneys in this case: Customer Number 23460.

23460

Please direct correspondence concerning this application to Leydig, Voit & Mayer, Ltd.: Customer Number 23460.

23460

I have reviewed the assignment records and certify that, to the best of my knowledge and belief, title of the original patent is vested in the United States of America as represented by the Secretary of the Department of Health and Human Services, as evidenced by the assignment recorded on August 28, 1990, beginning at Reel 5416, Frame 0858, of the Assignment Division Records in the U.S. Patent and Trademark Office.

I am authorized to sign this document on behalf of the assignee, inasmuch as the National Institutes of Health, Office of Technology Transfer, has been duly delegated responsibility for patent matters under the authority of DHHS Secretary Louis W. Sullivan's May 21, 1991, memorandum published in the Friday, June 7, 1991, Federal Register Notices at Vol. 56, Pages 26418-26419 (copy attached).

I declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 3.19.04

By: Richard U. Rodriguez
Richard U. Rodriguez, Reg. No. 45,980
Supervisor, Cancer Group
Office Of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852-3804
US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Reissue of U.S. Patent No. 6,114,397
Flack et al.	Issued: September 5, 2000
Application No. Unassigned	Art Unit: Unassigned
Filed: Herewith	Examiner: Unassigned
Assigned to: The United States of America as represented by the Secretary of the Department of Health and Human Services	
For:	GOSSYPOL FOR THE TREATMENT OF CANCER

CONSENT OF ASSIGNEE AND 37 CFR 3.73(b) STATEMENT

Mail Stop Reissue
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

THE UNITED STATES OF AMERICA, AS REPRESENTED BY THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, the assignee of the entire right, title and interest in the above-referenced United States patent, hereby consents to the reissue thereof, application for which is being filed herewith. Title is vested in the name of THE UNITED STATES OF AMERICA, AS REPRESENTED BY THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, by virtue of the assignment recorded on August 28, 1990, at Reel 5416, Frame 0858, as evidenced by the Notice of Recordation of Assignment for U.S. Application No. 07/551,353 (the application to which the instant patent claims priority) submitted herewith.

Date: 3-19-04

By: Richard U. Rodriguez
Richard U. Rodriguez, Reg. No. 45,980
Supervisor, Cancer Group
Office Of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852-3804
US

The person whose signature appears above is authorized to sign this document on behalf of the assignee, inasmuch as the National Institutes of Health, Office of Technology Transfer, has been duly delegated responsibility for patent matters under the authority of DHHS Secretary Louis W. Sullivan's May 21, 1991, memorandum published in the Friday, June 7, 1991, Federal Register Notices at Vol. 56, Pages 26418-26419.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard
Rockville, MD 20852

February 2, 2004

Nicholas P. Godici
Commissioner for Patents
U.S. Patent and Trademark Office (USPTO)
2121 Crystal Drive
Crystal Plaza #2 – Suite 910
Arlington, Virginia 22202

Re: Delegation of Authority for Certain Patent Administration and Prosecution Activities

Dear Sir:

Effective this date and acting under the authority set forth in DHHS Secretary Louis W. Sullivan's May 21, 1991 memorandum appearing in the Friday, June 7, 1991 Federal Register Notices at Volume 56, Number 110, pages 26418-26419 (copy attached), I authorize:

Astor, Marlene (Reg. No. 46,005);
Berkley, Dale (Reg. No. 42,319);
Ferguson, Steven (Reg. No. 38,448);
Finley, Stephen (Reg. No. 36,357);
Haight, James C. (Reg. No. 25,588);
Joyce, Catherine M. (Reg. No. 40,668);
Kim, John Peter (Reg. No. 38,514);
Kindra, Jasbir (Reg. No. 41,115);
Pontzer, Norbert (Reg. No. 40,777);
Rodriguez, Richard U. (Reg. No. 45,980);
Rucker, Susan S. (Reg. No. 35,762);
Sadowski, David R. (Reg. No. 32,808);
Schmickel, David (Reg. No. 40,270);
Shmilovich, Michael A. (Reg. No. 45,634); and,
Spiegel, Jack (Reg. No. 34,477)

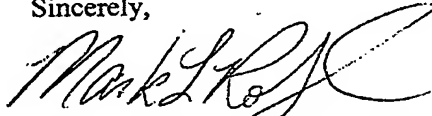
to exercise full authority in United States or International patents or patent applications in which the Government of the United States of America, as represented by the Secretary, Department of Health and Human Services, is an applicant or has an ownership interest with respect to the following:

- ☐ Signing original, associate, or substitute powers of attorney before the U.S. or International Authorities;
- ☐ Signing Request Forms, Demand Forms, and other documents filed in applications before the International Authorities;

Page 2: Delegation of Authority for Certain Patent Administration and Prosecution Activities

- ☐ Signing assignee's consent to changes in inventorship;
- ☐ Signing papers required from an assignee in connection with an application for Re-issue and/or Re-examination of a patent;
- ☐ Signing terminal disclaimers including, but not limited to, terminal disclaimers to obviate obviousness-type double patenting rejections; and,
- ☐ Signing all documents before the USPTO, either as the U.S. National Office or as a designated Receiving Office under the Patent Cooperation Treaty that can be signed by an assignee in patent matters.

Sincerely,



Mark L. Rohrbaugh, Ph.D., J.D.
Director
(Reg. No. 43,055)

Attachment

cc:

James J. Groody (PTO)
OTT Staff

Citation
56 FR 26418-02
1991 WL 300366 (F.R.)
(Cite as: 56 FR 26418)

Found Document

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FR

NOTICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the General Counsel; Statement of Organization, Functions and Delegations of Authority

Friday, June 7, 1991

*26418 Part A, chapter AG (Office of the General Counsel, Office of the Secretary) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (39 FR 17033, June 20, 1973, as amended most recently in pertinent part at 55 FR 17500, April 25, 1990), and part H, chapter HN (National Institutes of Health, Public Health Service) (40 FR 22859, May 27, 1975, as amended most recently in pertinent part at 55 FR 35366, August 29, 1990), are amended to:

(1) Delete the Department Patent Officer (AG.35) and transfer patent administration and prosecution responsibilities from this Officer to the Office of Technology Transfer (HNA432), Office of Intramural Affairs (HNA43), Office of Intramural Research (HNA4), Office of the Director (HNA), National Institutes of Health (HN), Public Health Service (H). Patent administration and prosecution activities will be consolidated with patent licensing functions within a single NIH organizational entity in order to improve program and resource management; and

(2) Retain patent legal services of the Department Patent Officer (AG.35) in the Public Health Division (AG.22.6), Office of the General Counsel, Office of the Secretary, and update the functional statement for the Public Health Division to reflect its responsibilities more accurately.

Office of the Secretary

Under Chapter AG, Office of the General Counsel, Sections AG.35 (Department Patent Officer) and AG.22.6 (Public Health Division), delete the titles and statements in their entirety and substitute the following:

Public Health Division (AG.22.6). The Public Health Division shall provide legal services, including patent legal services, for programs administered by the Public Health Service (except the Food and Drug Administration), e.g., the Office of the Assistant Secretary for Health, and the agencies and offices of the Public Health Service (other than FDA), including the Office of Technology Transfer and the Patent Policy Board.

Public Health Service

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56 FR 26418-02
(Cite as: 56 FR 26418, *26418)

Under Chapter NN, National Institutes of Health, Section HNA, Office of the Director, Office of Intramural Affairs (HNA43), add the following title and statement:

Office of Technology Transfer (HNA432). (1) Develops policy and procedures for NIH, ADAMHA, and CDC to follow for the implementation of Cooperative Research and Development Agreements (CRADAs), patent licenses, and other technology transfers; (2) implements Patent Policy Board decisions and policies; (3) drafts, negotiates, and periodically revises model forms and agreements; (4) provides advice to ICDS on problem licenses and agreements; (5) develops policy statements on various technology transfer issues such as conflicts of interest; (6) tracks the OTT budget and prepares an annual status report to the NIH Office of the Director; (7) provides coordination and management of goals, functions, and operations of the Technology Management Branch, Technology Licensing Branch, and the Technology Transfer Coordination Branch; (8) coordinates and provides planning and liaison support for *26419 international CRADAs and technology transfers; (9) creates and implements special programs relating to technology transfer by State and local governments and universities; (10) drafts and presents Congressional testimony, and drafts technology transfer-related responses to other Congressional inquiries; (11) provides operational management activities; (12) assists the Office of the General Counsel (OGC) in evaluating patent-related litigation matters; (13) in consultation with OGC and the involved agency component, as appropriate, negotiates settlements on contested matters with licensees or other parties involved with NIH, ADAMHA, and CDC in technology transfer or utilization matters; (14) represents the NIH, ADAMHA, and CDC in technology transfer or utilization matters; (15) represents the above agencies at a variety of professional conferences and other public fora; (16) investigates special issues; (17) evaluates the need for and develops new programs in technology management and technology transfer for the above agencies; (18) develops licensing strategies for NIH/ADAMHA/CDC intramural and CRADA inventions; (19) negotiates licenses and other technology transfers; (20) works with scientist inventors, contract attorneys and others in preparing patent applications and prosecuting these applications at the Patent Office level; (21) handles infringements in consultation with the OGC at the Patent Office level; and (22) makes recommendations to the OGC for referral of matters to the Department of Justice.

Dated: May 21, 1991.

Louis W. Sullivan,

Secretary.

[FR Doc. 91-13423 Filed 6-6-91; 8:45 am]

BILLING CODE 4150-04-M

56 FR 26418-02, 1991 WL 300166 (F.R.)
END OF DOCUMENT

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